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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/855,287 | 05/15/2001 | Arthur C. Coffey | 7175-67882 | 1909 |

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615 | 8 |

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|-----------------|-------------------|
| | 09/855,287 | COFFEY, ARTHUR C. |
| Examiner | Art Unit | |
| Lakshmi S Channavajjala | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,6-9,14-18,27,28,30-37 and 39-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,6-9,14-18,27,28,30-37 and 39-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) Other: _____

DETAILED ACTION

Receipt of amendment B, dated 12-26-02 is acknowledged.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6-9, 14-18, 27, 28, 30-37 and 39-43 are have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta in view of US 5,759,570 to Arnold.

Instant claims are directed to a wound care bandage comprising a collagen matrix, a cover to seal the wound that is adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the wound cover. The collagen matrix in the instant claims is placed on the wound surface.

Argenta teaches a method of treating tissue damage in burns and wounds (abstract, col. 1, lines 55-65). The apparatus of Argenta comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound and a screen means to prevent overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous, configured to be placed over a wound, into which is inserted a flexible tube for attachment to a suction pump. The sealing means comprises a polymeric sheet above the foam section and tubing such that it is adhered to the skin surrounding the wound (col. 2, lines 15-28). Argenta teaches that the screen means is a semi-rigid structure and is directly connected to the vacuum source (col. 4, lines 29-60) and the screen means reads on the instant structure placed

between the collagen matrix and the cover. Argenta teaches application of pressure in cycles in alternate periods of application and non-application (col. 3, lines 9-18). Further, Argenta teaches that the method of applying negative pressure enables increased blood flow into the wound area, reduces the bacterial infection in the area and thus enhances wound healing and (col. 3, lines 29-46), which is also claimed in the instant method claims.

Argenta lacks a collagen layer in contact with the wound, as in the instant claims.

Arnold teaches a multilayer wound dressings for the treatment of damaged, burned, ulcerated or otherwise traumatized mammalian skin. The wound dressing of Arnold comprises a wound contacting layer comprising a bioabsorbable and hydrophilic polymeric material such as collagen (col. 4 lines 21-57). This layer is similar to the instant collagen matrix, obtained from natural sources (col. 5). The wound contact layer absorbs wound exudates, provides a biocompatible wound-friendly environment and form a bioabsorbable gel i.e., integrates into the wound. The wound contact layer is attached to a molecular filtration membrane, which is liquid permeable of defined pore size (col. 3). The membrane is attached to the body over a wound site by a pressure-sensitive adhesive (col. 3, lines 22-40). The wound dressing of Arnold further comprises an absorbent layer on top of the molecular filtration membrane, which further absorbs the absorbents wound exudates through the membrane and are held in place by a final protective covering on the dressing so that the exudates do not leak and the bed or clothes are not spoiled (col. 3, lines 40-47). The absorbent layer overlying the molecular filtration membrane may include a pharmaceutical, a wound-healing agent, a growth factor or a microbiocide etc. The absorbent layer of Arnold reads on the instant structure "c".

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add a collagen wound contact layer of Arnold in the vacuum assisted therapy for wound healing of Argenta because Arnold teaches that collagen when placed in contact with the wound in the wound dressing forms a wound contacting layer and forms a bioabsorbable gel upon contact with the wound exudates and also acts as a slow relelease matrix for the relelease of wound healing agents such as the growth factors, cytokines, antibiotics etc (paragraph bridging col. 4-5). Accordingly, by placing one or several layers of collagen as a wound contacting layer in the structure of Argenta, an ordinary skill in the art would have expected to relelease the fibroblast growth factor or other wound healing promoting and infection reducing agents to release from collagen matrix for a sufficient period of time so as to ensure complete and thorough healing of the wound. Further, upon applying vacuum one of an ordinary skill in the art would have expected the exudates (including blood) to draw from wound in to collagen and that collagen integrates in to the wound over a period of time. Further, while neither reference teach the specific ring shaped structure of claims 14 and 32, both Argenta and Arnold teach the same porous material and for the same purpose i.e., absorb exudates. Therefore, using an appropriate shaped structure of the pad, without altering the recognized function would have been within the scope of a skilled artisan. Examiner notes that the figure 1 and the description of figure 1 in Arnold reads on the claimed structural requirements of the instant wound dressing.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta in view of US 5,759,570 to Arnold as applied to claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-43 above, and further in view of US 6,440,427 to Wadstrom.

The wound dressings of Argenta and Arnold, discussed above, do not contain instant fibrin glue for holding collagen matrix.

Wadstrom teaches tissue treatment composition comprising fibrin or fibrinogen, and biodegradable polymers for wound healing or slow-release drug formulations etc (col. 1, lines 12-15). Wadstrom teaches fibrin is a known biological adhesive and is mixture of fibrin and thrombin that forms a coagulum (col. 1, lines 23-30). Wadstrom teaches fibrin sealants act in several ways, in hemostasis, glueing and wound healing. Further, Wadstrom teaches that fibrin sealants are used in a number of fields, especially for wound healing and prevention of adhesion of adjacent tissues (col. 3, lines 37-48).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the fibrin sealant of Wadstrom in the wound dressing of Argenta, containing collagen of Arnold (Argenta) because Wadstrom suggests that fibrin glue, due it adhesive properties, is capable of atraumatically connecting tissues by forming a strong joint between them and adapts uneven wound surfaces, promotes in growth of fibroblasts, which in combination with efficient hemostasis and adhesion between the wound surfaces provides for an improved healing process. Further, Wadstrom teaches that fibrin glueing effect is increased by fibronectin binding to exposed collagen (col. 1, lines 57 through col. 2, lines 15). Accordingly, one of an ordinary skill in the art would have expected to increase the homeostasis and fibroblast growth at the wound-healing site, by placing fibrin glue close to collagen layer in the wound dressing of Argenta.

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 26, 2003